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TO AMEND THE FEDERAL FOOD, DRUG AND COSMETIC ACT

HEARINGS

BEFORE A

SUBCOMMITTEE OF THE COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE HOUSE OF REPRESENTATIVES

EIGHTY-FIRST CONGRESS

FIRST SESSION

ON

H. R. 3151

A BILL TO AMEND THE FEDERAL FOOD, DRUG, AND COSMETIC ACT OF JUNE 25, 1938, AS AMENDED, BY PROVIDING FOR THE CERTIFICATION OF BATCHES OF DRUGS COMPOSED WHOLLY OR PARTLY OF ANY KIND OF AUREOMYCIN, CHLORAMPHENICOL, AND BACITRACIN, OR ANY DERIVATIVE THEREOF

H. R. 562

A BILL TO AMEND SECTION 801 (d) OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT, AS AMENDED, IN RELATION TO EXPORTS

H. R. 160

A BILL TO AMEND SECTION 801 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT, AS AMENDED

APRIL 12, 28, AND MAY 2, 1949

Printed for the use of the Committee on Interstate and Foreign Commerce

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UNITED STATES
GOVERNMENT PRINTING OFFICE
80509 WASHINGTON : 1949

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TO AMEND THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

TUESDAY, APRIL 12, 1949

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON SEC, FCC, AND FTC, OF THE
COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE,
Washington, D. C.

The subcommittee met at 10 a. m., Hon. George G. Sadowski (vice chairman of the subcommittee) presiding.

Mr. SADOWSKI. The committee will please be in order. The committee has met this morning to conduct hearings on certain Food and Drug Administration bills. The first bill we shall take up this morning is H. R. 3151, introduced by Mr. Priest: To amend the Federal Food, Drug, and Cosmetic Act of June 25, 1938, as amended, by providing for the certification of batches of drugs composed wholly or partly of any kind of aureomycin, chloramphenicol, and bacitracin, or any derivative thereof.

A copy of the bill will be inserted in the record at this point.

(H. R. 3151 is as follows:)

[H. R. 3151, 81st Cong., 1st sess.]

A BILL To amend the Federal Food, Drug, and Cosmetic Act of June 25, 1938, as amended, by providing for the certification of batches of drugs composed wholly or partly of any kind of aureomycin, chloramphenicol, and bacitracin, or any derivative thereof

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That section 502 (l) of the Federal Food, Drug, and Cosmetic Act of June 25, 1938, as amended (U. S. C., 1946 edition, title 21, ch. 9), is amended by deleting the word "or" preceding the word "streptomycin" and inserting in lieu thereof a comma and by inserting after the word "streptomycin" the following: ", aureomycin, chloramphenicol, or bacitracin,".

SEC. 2. (a) The heading of section 507 of such Act, as amended, is amended by deleting the word "OR" preceding the word "STREPTOMYCIN" and inserting in lieu thereof a comma and by adding at the end of such heading the following: ", AUREOMYCIN, CHLORAMPHENICOL, OR BACITRACIN".

(b) The first sentence of subsection (a) of such section 507 is amended by deleting the word "or" preceding the word "streptomycin" and inserting in lieu thereof a comma and by inserting after the word "streptomycin" the following: ", aureomycin, chloramphenicol, or bacitracin,".

Mr. SADOWSKI. The committee has reports from the Federal Security Agency and the Secretary of Commerce and the Federal Trade Commission on this bill, which will be made a part of the record at this point.

(The matter referred to is as follows:)

FEDERAL SECURITY AGENCY,
Washington 25, March 25, 1949.

Hon. ROBERT CROSSER,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D. C.

DEAR MR. CHAIRMAN: This letter is in reply to your request of March 5, 1949, for a report on H. R. 3151, a bill to amend the Federal Food, Drug, and Cosmetic

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Act of June 25, 1938, as amended, by providing for the certification of batches of drugs composed wholly or partly of any kind of aureomycin, chloramphenicol, and bacitracin, or any derivative thereof."

This bill would amend sections 502 and 507 of the Federal Food, Drug, and Cosmetic Act so as to provide for aureomycin, chloramphenicol, and bacitracin, three new "miracle" drugs, and their derivatives, the same certification procedure now required in the case of penicillin, streptomycin, and insulin. The bill is identical with a draft bill which we submitted with our letter of February 21, 1949, to the Speaker of the House of Representatives, a copy of which is enclosed for your convenience.

As appears from the enclosed letter, the amendment is essential to protect patients against a dangerous departure of new drugs from standards of identity, strength, quality, and purity appropriate to their safe and efficacious use. As we have indicated, it is recognized by the manufacturers of these drugs that pretesting and certification is necessary not only for the protection of the public health, but for their own protection as well. As a matter of fact, the three large producers of these drugs have requested that steps be taken to establish a certification system for aureomycin, bacitracin, and chloramphenicol similar to that now in effect for penicillin and streptomycin.

We therefore urge the enactment of this measure. As stated in the enclosed letter, the Bureau of the Budget has advised that there is no objection to the submission of this legislation to the Congress.

Sincerely yours,

J. DONALD KINGSLEY,
Acting Administrator.

FEDERAL SECURITY AGENCY,
Washington, February 21, 1949.

The honorable the SPEAKER OF THE HOUSE OF REPRESENTATIVES,
Washington, D. C.

DEAR MR. SPEAKER: As you know, the Federal Food, Drug, and Cosmetic Act contains provisions in section 507 and related sections requiring that penicillin and streptomycin, and all products containing them, be pretested by the Government and certified before interstate distribution.

The reasons underlying the requirements for certification of penicillin and streptomycin are that they are highly efficacious in many serious diseases suffered by large numbers of our population, that unusual difficulties are inherent in their manufacture, that the methods for testing finished lots for determining safety and efficacy are not yet entirely satisfactory, and that there exists an unusual likelihood that lots will appear on the market which are not of the appropriate strength, quality, and purity. It requires not only the greatest care on the part of the manufacturer to insure that the product is what it should be, but check testing by a disinterested and competent authority as well.

During the past few years a number of new drugs have been developed which have effects on specific diseases similar to those demonstrated for penicillin and streptomycin. The dramatic effects produced by these new antibiotics, shown in the treatment of serious and often fatal diseases, are demonstrated daily. Each of these new antibiotics is effective in certain diseases and not in others. For example, penicillin is very effective in the treatment of pneumococcic infections and streptococcic infections, while streptomycin has been found extremely useful in the treatment of tuberculosis. There has been a constant search for new antibiotics which will broaden the effectiveness of these drugs.

The new drugs about which this letter is concerned, aureomycin, chloramphenicol, and bacitracin, have successfully broadened the field to include a number of diseases not heretofore amendable to treatment. For example, aureomycin has been found valuable in the treatment of certain rickettsial diseases, such as Rocky Mountain spotted fever and scrub typhus, and has been found successful in the treatment of primary atypical pneumonia, a disease for which we have never had a satisfactory cure. Similarly, chloramphenicol has been found valuable in the treatment of both rickettsial and virus diseases, but in addition has proved to be extremely valuable in the treatment of typhoid fever. Bacitracin has been utilized against certain diseases which have been found to react favorably to treatment with penicillin. The last-named drug is used primarily for topical application, because of inherent toxic properties.

These drugs, like penicillin and streptomycin, are produced by the growth of microorganisms, and their manufacture and testing are subject to the same kind

of unexplained vagaries that characterize the production of all biological products. Because of the toxicity of bacitracin, in some instances at least, the need for predistribution checking is even greater than with penicillin.

The certification procedure we are now recommending for aureomycin, chloramphenicol, and bacitracin has precedent in the terms of the Federal Food, Drug, and Cosmetic Act, not only in the penicillin and streptomycin provisions but in the provisions of section 506, which requires certification of insulin, the drug which enables diabetics to live a nearly normal span of life. In common with penicillin, streptomycin, and insulin, aureomycin, chloramphenicol, and bacitracin present problems of a common pattern in the importance of their need for effective control in the interest of public health. They are all highly efficacious for one or more serious diseases; they all present unusual difficulties in the process of manufacture and the methods of testing finished lots, and for this reason are prone to depart from standards of identity, strength, quality, and purity appropriate to insure safety and efficacy of use.

The general provisions of the law applicable to other drugs are quite ineffective in meeting the needs of public protection presented by these articles. There is no authority in these general provisions for testing by the Government before distribution even where the manufacturer desires such testing as an insurance against mistakes. Examinations can be made only after the products are shipped or offered for shipment in interstate commerce. With the sanctions of seizure, criminal prosecution, and injunction contained in the act, and the facilities available for enforcement, only a fraction of the output of any drug can ordinarily be given attention and proceeded against effectively when it fails to meet appropriate standards. Seizure of widely dispersed products is possible in only a relatively small proportion of cases. Criminal prosecution and injunction proceedings do not benefit the patients who have received ineffective or toxic drugs contained in the shipments upon which such actions are instituted.

It is probable that as improved techniques in manufacture and better methods of testing are developed, the need for pretesting and certification of aureomycin, chloramphenicol, and bacitracin may no longer exist. That probability with respect to penicillin and streptomycin was recognized in section 507 (c), which directs the Administrator to promulgate regulations exempting the drug from certification requirements when that procedure is not necessary to insure safety and efficacy of use. This provision would apply equally to aureomycin, chloramphenicol, and bacitracin if the recommended amendment is adopted.

A draft of the amendment is attached. This proposed legislation has been discussed with representatives of members of the industry who produce aureomycin, chloramphenicol, and bacitracin or who may be concerned with its production. There appears to be no significant opposition to the proposal. In fact, the present basic producers of aureomycin, chloramphenicol, and bacitracin have requested that steps be taken to establish a certification service for their products similar to that now being utilized for penicillin and streptomycin. The cost of establishing and maintaining the certification service, as with penicillin and streptomycin, will be borne by the manufacturing industry through payment of appropriate fees.

The Bureau of the Budget advises that there is no objection to the submission of this proposed legislation to the Congress for its consideration.

Sincerely yours,

OSCAR R. EWING, *Administrator.*

THE SECRETARY OF COMMERCE,
Washington 25, April 5, 1949.

Hon. ROBERT CROSSER,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D. C.

DEAR MR. CHAIRMAN: This letter is in reply to your communication of March 5, 1949, requesting the Department's comments on H. R. 3151, a bill to amend the Federal Food, Drug, and Cosmetic Act of June 25, 1938, as amended, by providing for the certification of batches of drugs composed wholly or partly of any kind of aureomycin, chloramphenicol, and bacitracin, or any derivative thereof.

The proposed bill would amend the Federal Food, Drug, and Cosmetic Act of June 25, 1938, by providing for the certification of drugs composed wholly or partly of any kind of aureomycin, chloramphenicol, and bacitracin.

I am of the opinion that enactment of this amendment would provide a very desirable broadening of the certification requirements presently set forth in section 502 (1) of the Federal Food, Drug, and Cosmetic Act.

I have been advised by the Bureau of the Budget that there is no objection to the submission of this report to the committee for its consideration.

Sincerely yours,

CHARLES SAWYER,
Secretary of Commerce.

FEDERAL TRADE COMMISSION,
OFFICE OF THE CHAIRMAN,
Washington, March 30, 1949.

Hon. ROBERT CROSSER,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D. C.

MY DEAR MR. CHAIRMAN: This is with further reference to your letter of March 5, 1949, enclosing a copy of H. R. 3151, Eighty-first Congress, first session, entitled "A bill to amend the Federal Food, Drug, and Cosmetic Act of June 25, 1938, as amended, by providing for the certification of batches of drugs composed wholly or partly of any kind of aureomycin, chloramphenicol, and bacitracin, or any derivative thereof," introduced March 2, 1949, by Representative James Percy Priest of Tennessee, and requesting a prompt report, together with such comment as the Commission may desire to make concerning the proposed legislation. In response thereto, I wish to advise that the bill has been carefully examined and the following comment is submitted by the Commission for the information of your committee:

Aureomycin, chloramphenicol, and bacitracin are antibiotic drugs having exceptional value in the treatment of certain diseases of animals and man. It is important that these antibiotic drugs and their derivatives have the potency claimed for them. Since the manufacture of these preparations involves complicated technical procedures, it is in the interest of the public to have each batch of each of these antibiotic drugs and each derivative thereof certified as to identity, strength, quality and purity, in order to insure safety and efficacy of use.

Members of the staff of the Federal Trade Commission have followed carefully the discovery and development of these antibiotics and know their usefulness has been established in a number of communicable diseases in which neither penicillin nor streptomycin have curative value. It appears, therefore, that in order to assure uniform potency and to achieve the greatest possible safety and benefit to health in the use of these antibiotics, each manufactured batch of each preparation containing one or more of these drugs or their derivatives should be properly tested and certified before it is distributed in commerce. H. R. 3151 makes provision for such testing and certification, and its enactment will be in the public interest.

By direction of the Commission.

With kind personal regards, I am

Sincerely yours,

LOWELL B. MASON, *Acting Chairman.*

APRIL 4, 1949.

N. B.—Pursuant to regulations, this report was submitted to the Bureau of the Budget on March 30, and on April 1, 1949, the Commission was informed by telephone that there would be no objection to the presentation of the report to the committee.

LOWELL B. MASON, *Acting Chairman.*

Mr. SADOWSKI. We are pleased to receive a statement by the author of the bill, Mr. Priest, at this time.

STATEMENT OF HON. J. PERCY PRIEST, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TENNESSEE

Mr. PRIEST. The bill H. R. 3151, which I have introduced, would amend the Federal Food, Drug, and Cosmetic Act to include three new antibiotic drugs—aureomycin, chloramphenicol, and bacitracin—under the same certification system authorized by Congress for penicillin in 1945 and for streptomycin in 1947.

These antibiotics are produced by the growth of micro-organisms. Their manufacture and testing are subject to the same kind of unexplained vagaries that characterize the production of all biological products. Because these drugs are highly effective in the treatment of serious and often fatal diseases and because of the difficulties associated with available methods of testing them for strength and purity, it is necessary to public protection that the Government check-test each batch before it is marketed and certify it if it measures up to standard.

An article in the Washington Post of March 1, 1949, tells a dramatic story of how aureomycin was used to save the lives of twin babies suffering from bronchial pneumonia. In the treatment of infants especially it is paramount that the precise strength and purity of the drug be known. Doctors are dependent upon the guaranty of the label. Aureomycin has been used successfully in the treatment of primary atypical pneumonia, a disease for which we have never had a cure, and in certain rickettsial diseases such as Rocky Mountain spotted fever and scrub typhus. The drug is also used in the treatment of relapsing fever and certain eye infections.

Chloramphenicol has been valuable in treatment of certain rickettsial and virus diseases and, in addition, has proved to be extremely valuable in the treatment of typhoid fever. A London dispatch describes the highly effective use of this drug in treating British troops in Malaya who were suffering from scrub typhus, a disease that has been a scourge to British soldiers in the Far East.

Bacitracin has been used to treat certain diseases that resist the action of penicillin. Recent work has demonstrated its value in various ocular infections and in the treatment of amoebic dysentery—a disease of widespread incidence in the United States.

As production increases and these drugs become more available to clinicians for study, undoubtedly other diseases will be discovered that are amenable to treatment with them.

It is of great importance to public health that these three new antibiotics be subjected to a final testing by the Government before distribution to the consumer. This bill provides for the establishment of such a program.

Mr. SADOWSKI. We will now hear from Dr. Dunbar, Commissioner of Food and Drugs, on the bill H. R. 3151.

STATEMENT OF DR. P. B. DUNBAR, COMMISSIONER OF FOOD AND DRUGS, FOOD AND DRUG ADMINISTRATION

Dr. Dunbar, do you have a statement to make on H. R. 3151?

Dr. DUNBAR. A very brief statement, Mr. Chairman.

Mr. SADOWSKI. You may proceed.

Dr. DUNBAR. Mr. Chairman and gentlemen of the committee, the Federal Security Agency recommends your favorable consideration of the bill H. R. 3151. This bill would apply to three new antibiotic drugs the pretesting and certification procedures now provided for penicillin and streptomycin through amendments to the law developed in this committee in 1945 and 1947.

Members of the committee will recall the reasons underlying the requirements for certification of penicillin and streptomycin. The drugs are spectacularly efficacious in many serious diseases suffered

by large numbers of our population. They are produced by biological processes and are assayed by biological methods. Both the production and the testing of the drugs are therefore subject to the vagaries inherent in practically all biological procedures and there is unusual likelihood that lots will appear on the market which are not of the appropriate strength, quality, and purity unless, even when the greatest care is taken by the manufacturer, individual batches of the drugs are check-tested by a disinterested and competent authority.

The development of penicillin, which is produced by the metabolism of a certain species of mold, opened the door to a series of new and highly efficacious therapeutic agents produced by other microorganisms. The latest of these which have now reached the stage of commercial production are aureomycin, chloramphenicol, and bacitracin. It is these new drugs for which the bill would authorize certification procedure. Each is effective against diseases not heretofore amenable to treatment with penicillin, streptomycin, or any other known drugs.

For example, aureomycin has been used successfully in treating primary atypical (virus) pneumonia and certain Rickettsial diseases such as Rocky Mountain spotted fever and scrub typhus. It is also used in the treatment of relapsing fever and certain eye infections.

Chloramphenicol is valuable in the treatment of certain Rickettsial and virus diseases and has proved valuable in typhoid fever. Like aureomycin, it is also effective for scrub typhus.

Recent work on bacitracin has demonstrated its value in various infections of the eye and in amoebic dysentery—a disease of wide incidence in the United States.

As production increases and these drugs become more available to clinicians for study, other diseases will undoubtedly be discovered for which they are effective.

It is of great importance to the public health that batches of these three new antibiotics be subjected, as penicillin and streptomycin now are, to a final testing by the Government before they are distributed for use. Provisions of the present law, except those relating to penicillin and streptomycin, are ineffective in meeting the needs of public protection presented by these articles.

There exists now no authority for governmental testing before distribution even where the manufacturer desires it. Examinations can be made only after the products are shipped or offered for shipment in interstate commerce. Under the sanctions of seizure, criminal prosecution, and injunction contained in the act, and the facilities available for enforcement, only a fraction of the output of any drug can ordinarily be given attention and proceeded against effectively when it fails to meet appropriate standards.

The present basic producers of aureomycin, chloramphenicol and bacitracin have requested that provisions be made for certifying these products. The cost of the service, as is the case with penicillin and streptomycin, would be borne by the producers through payment of appropriate fees.

Mr. SADOWSKI. Are there any questions, gentlemen?

Mr. WILSON. Doctor, what are the fees that are paid by the producer? They are paid by the producer, as I understand?

Dr. DUNBAR. That is right. They vary with the amount of testing which is required for the particular drug. I have here a list of the fees charged for the various types of penicillin drugs.

For example, the fee assessed now per vial of regular penicillin is $1. The fees are adjusted to take care of the actual cost of pretesting and certification. If you should like, I should be glad to file for the record a complete statement of the charges in each particular case.

Mr. WILSON. There is no complaint on the part of the industry that produces these products, is there?

Dr. DUNBAR. None whatever.

Mr. DOLLIVER. Doctor, I am not very familiar with the procedure of making these tests. Would you describe that for the benefit of those of us who do not understand it?

Dr. DUNBAR. As I stated in my prepared remarks, we use what are known as biological processes. That means that we test these products on various animals and on various bacteria to determine the effect on the particular organism of this drug. Perhaps I can answer your question, Mr. Dolliver, in simplest terms, by describing what we do with penicillin.

Mr. DOLLIVER. That is what we should like.

Dr. DUNBAR. Penicillin was the first of these wonder drugs and it is perhaps one of the miracles of the war that the first one that was developed was one of the most potent that has been so far discovered and was responsible for saving innumerable lives from the time in 1943 or 1944 when it first became available for wounded men, men wounded during hostilities.

In order to test the effectiveness of the drug against bacteria, there is a standard procedure by which we establish the zone of bacterial inhibition. Plates of this general type with culture mediums, flat plates, culture plates, are prepared.

Mr. DOLLIVER. Those are made out of glass?

Dr. DUNBAR. Those are made out of glass. They are flat glass plates of about 3 inches diameter. Then there is a gelatin agar solution put on that plate and then there are small metal tubes of calibrated size holding 1 cubic centimeter. The tubes are placed in a circle around the edges of the plate containing the agar. In two of those are placed a standard solution of penicillin of known strength. In the other three are placed various dilutions of the test sample that we have under examination.

This agar is infected with a certain organism, a test organism. The inhibiting effect of the penicillin is then manifested on this plate by a clear circular zone in the culture medium where the bug failed to develop and the diameter of that circle of inhibition, that clear space, has a precise ratio to the strength of the penicillin, the potency of the penicillin.

In other words, we compare the diameter of the circle of the inhibition where the bacteria do not grow, produced by the standard penicillin, with the diameter of the test solution and if they are exactly the same, then we know that the product is of the same potency as the standard sample. That is our technique on penicillin for determining potency.

In addition to that, we have to determine certain toxicity factors. One of those factors is pyrogenicity. That is the presence of impurities that cause elevated temperatures in patients. That is done by using rabbits as test animals. The injections are made in the ear of the rabbit, which is kept in a fixed position by a series of stocks. As a matter of fact, these rabbits live for years. They are getting

doses of penicillin continuously and they are perfectly comfortable and happy.

After a certain period of time, the rectal temperature of the rabbit is determined in order to find whether there has been any elevation of temperature due to the administration of this drug.

Then there are certain other toxicity tests. We use white mice for acute toxicity tests; certain determinations of moisture are also made. That is about the list of them.

The testing depends upon the character of the particular preparation and it will vary; that is, the streptomycin tests will differ from those of penicillin. But I think that perhaps gives you a sufficient idea of what our tests are.

Mr. DOLLIVER. That is precisely what I wanted to know, Doctor. One further question along that line, which reveals my ignorance of this subject, perhaps. How large a sample is taken from any given quantity to test? How large a sample of penicillin or streptomycin is taken?

Dr. DUNBAR. I am going to ask Mr. Jester of our Penicillin Division to help me out. You are getting me a little off base now.

Mr. DOLLIVER. I do not mean to be too technical, but this is a matter of interest to us.

Dr. DUNBAR. Mr. Jester, will you explain in answer to Mr. Dolliver's question? You may be able to supplement my statement on costs, also.

Mr. SADOWSKI. For the purpose of the record, please state your name and your position.

STATEMENT OF WILLIAM R. JESTER, DIVISION OF PENICILLIN, FOOD AND DRUG ADMINISTRATION

Mr. JESTER. My name is William R. Jester of the Penicillin Division, Food and Drugs Administration.

As to the cost, it varies in relation to the product. For instance, as to penicillin tablets, the minimum cost is $20, not less than 20 tablets, or more than 100 tablets from a batch. The cost per tablet in the sample is a dollar.

In vial penicillin, which is used for injections, the cost in that case is $4 per vial; the minimum cost is $10 and the maximum is $17. That is based on one of each 5,000 vials in a batch that is supposed to be a representative sample of the manufacturer's batch. Those costs are based on the actual cost of the examination.

Incidentally, we recently reduced the cost of fees, because the production of penicillin had gone to a point where we could reduce the fees, get them down commensurate with the actual cost.

Mr. DOLLIVER. Is it a fact, then—and I do not care which one of you gentlemen answers this question—is it a fact that the fees that you charge for these examinations actually cover the cost and there is, therefore, no cost to the taxpayers for this kind of work?

Dr. DUNBAR. That is true. I have some data here on the receipts from fees. We adjust the fees so that there is no actual cost to the taxpayers.

Mr. DOLLIVER. Do you have any figures that could be inserted in the record that would verify that statement? I think that would be of interest when we take the bill to the floor of the House, Mr. Chairman.

Dr. DUNBAR. For the fiscal year ending June 30, 1948, receipts from fees for penicillin control were $494,404. For the first half of the current fiscal year ending December 31, the receipts for penicillin control were $296,807. I can give you the receipts for the first 3 months of this current calendar year, if you would like to have them. I think Mr. Jester has them. They will give you an idea of what they amount to. Or we can insert them in the record, as you wish.

Mr. DOLLIVER. Mr. Chairman, the reason for my inquiry along this line is that I am sure some of the Members, when this legislation is offered, will ask what it is going to cost the Government; and I should like to be able to show in the hearings that this service is not costing the taxpayers anything.

I hope that the witness and his assistants can furnish us with figures which will demonstrate that, or that they may put those figures in the record. I do not want to pursue that line of questions any further, but would like to have the information in the record. Thank you.

Dr. DUNBAR. Mr. Congressman, the fees for January and February, on penicillin, were $106,000. May I say this, too, that this matter has been considered in the Appropriations Committee of the House and each year we report in full the receipts, report that to the Appropriations Committee. We now have authority to utilize the funds received and ask for no additional funds, use the funds received as a sort of revolving fund to support this work. And I can assure you most emphatically that the cost is fully borne by the manufacturers who submit their products for certification.

Mr. ROGERS. Doctor, who are the producers or the manufacturers of these particular drugs?

Dr. DUNBAR. Of these three that we are talking of this morning, Mr. Rogers?

Mr. ROGERS. Yes.

Dr. DUNBAR. The Lederle Laboratories are producers of aureomycin. The producers of chloramphenicol are Parke-Davis and the producers of bacitracin are Commercial Solvents and the Upjohn Co.

May I make one correction of a statement that I made previously? I stated that requests for certification legislation on these three antibiotics have been made by the manufacturers. That is true in the case of Lederle Laboratories and Commercial Solvents. I was wrong in stating that Upjohn had requested this amendment. However, they have agreed to it; and Parke-Davis, also.

Mr. SADOWSKI. Now, I understand there will be no special regulations as to these new drugs; they will be incorporated into the present statute which has to do with streptomycin?

Dr. DUNBAR. And penicillin.

Mr. SADOWSKI. And the same regulations will apply to these new drugs as now apply to streptomycin and the other drugs you have mentioned?

Dr. DUNBAR. The same type of regulation. Of course, we will have to prepare new specifications for these new drugs. But the same type of regulation will apply and the effect of this amendment will be merely to introduce into the sections of the law now covering penicillin and streptomycin the names of these three additional antibiotics.

Mr. WILSON. You have about how many examiners now?

Dr. DUNBAR. What is the number of your personnel in your laboratory, Mr. Jester?

Mr. JESTER. Seventy-two.

Dr. DUNBAR. That is the entire force.

Mr. WILSON. Will that be increased?

Dr. DUNBAR. Probably to some extent; yes, sir.

Mr. ROGERS. What are the relative costs of aureomycin and these other drugs compared to penicillin and streptomycin?

Dr. DUNBAR. You mean the market price?

Mr. ROGERS. Yes.

Mr. JESTER. The last figure on aureomycin was 75 cents a capsule. A capsule is 250 miligrams and the usual dosage is one every 6 hours for 4 or 5 days. That would give you an idea of the cost to the patient.

Mr. SADOWSKI. Are there any other questions?

Mr. HINSHAW. Doctor, we seem to be getting quite a long list of antibiotics. Goodness knows where that list may end with continued research and study.

Is it your idea that all of these antibiotics should be approved under standards set up for them by the Department?

Dr. DUNBAR. That is a very pertinent question, Mr. Hinshaw and I think it is true that we can anticipate the development of other very valuable antibiotics in the future. If the same conditions develop in the case of newly developed antibiotics that exist here—that is to say, biological tests with resulting vagaries—if the articles developed are of such value as a therapeutic agent as are the present ones, it would be my notion that it would be necessary or desirable to have similar amendments to cover the new ones.

On the other hand, I think the time will come—in fact, it probably is here now—when the expertness of the manufacturers has reached a point where they can develop a uniform and very potent product which will not vary materially from day to day. That situation has already been reached in the case of crystalline penicillin G and tomorrow's Register will publish a proposed announcement for decertification of penicillin G. But as new antibiotics are developed, I think the answer to your question is "yes," it would be desirable to bring them under certification.

Mr HINSHAW. The point of my question, of course, is obvious. Why should we not strike out the various names and merely insert "antibiotics"?

Dr. DUNBAR. The only answer to that, Mr. Hinshaw, is that there have been certain drafting difficulties presented in the formulation of a general antibiotic amendment of that type. We have been considering it very seriously. We have in fact attempted and are still attempting with a committee from the industry to draft such an amendment in general terms which would be acceptable to everybody. We have not yet reached that point, however, where there is a meeting of the minds sufficiently for us to feel that we should come before the committee and ask for that kind of an amendment. But we are working on it. In the meantime, the pressure for these three makes it highly desirable to have them put under the statute.

Mr. HINSHAW. May I ask a further question? The names that are given to these particular antibiotics are given to them by the scientists, is that right?

Dr. DUNBAR. That is right.

Mr. HINSHAW. We would have to have somewhere a definition of exactly what each one was, would we not?

Dr. DUNBAR. That is right.

Mr. HINSHAW. In some cases, it is not a term that is defined in the dictionary because usually these terms are newly coined, is that right?

Dr. DUNBAR. That is right. It is not defined in the dictionary. We will have to define it.

Mr. HINSHAW. Therefore, when you name such a product in an act, we are naming something which has been aptly named by somebody who discovered it?

Dr. DUNBAR. That is correct.

Mr. HINSHAW. On the other hand, the general term antibiotic, I suspect, is a term that is defined in the dictionary or in the encyclopedia, is that correct?

Mr. CROSSER. Does it not mean against life?

Dr. DUNBAR. That is right, Mr. Chairman. I have not looked it up in any of the new dictionaries, but the term, I believe, would hardly be more than 5 years old, because it was coined about the time penicillin came into the picture. And we did not begin to manufacture penicillin in the United States until the middle of the war, about 1943 or 1944.

So far as I know, the term was not previously used. It was coined to cover just this type of produce and, as Mr. Crosser says, means against life; that is, against the organisms that are injurious to life. I have never quite seen the consistency of the term. It seems to me that it is life-giving rather than being against life, it has such marvelous curative effects.

Mr. HINSHAW. On the other hand, it has such a general connotation in the industry that its definition could be considered to have been established; is that true?

Dr. DUNBAR. That is true, Mr. Hinshaw; yes, sir.

Mr. HINSHAW. And if any case went to the Supreme Court, for example, the Supreme Court could determine quite quickly exactly what was meant by that term?

Dr. DUNBAR. I do not know that I want to predict what the Supreme Court would do.

Mr. HINSHAW. It would be available in sources from which they could obtain a definition.

Dr. DUNBAR. That is correct; yes, sir.

Mr. HINSHAW. Is there any reason why any of these antibiotics that may be discovered to be of value should not likewise be included under the Food, Drug, and Cosmetic Act?

Dr. DUNBAR. None that I know of right now; no, sir.

Mr. HINSHAW. Is there any reason why they should be excluded?

Dr. DUNBAR. None that I know of, unless the situation exists such as I mentioned a moment ago, where the method of production is so precise that the article was of an invariable composition—that is, no variations; and where the testing was so readily accomplished that there could be little doubt that the product would meet the requirements as to purity at the time the original manufacturer produced it.

Mr. HINSHAW. But if we were to include the term as a general term, it could be controlled as you saw fit, as you are now proposing to do with one or two of them.

Dr. DUNBAR. That is correct; yes, sir.

Mr. HINSHAW. I was just wondering why that would not be the more proper thing for the committee to do, if it is going to do anything.

Dr. DUNBAR. Mr. Hinshaw, that is the approach we have been making to this particular amendment. As I say, we have run into some drafting difficulties, but the general idea was that if authority could be granted to the Administrator to hold hearings and take testimony as to a particular antibiotic, as to whether it should be produced under certification, that should be done; and also, that we should have authority to decertify, and then we would not be obliged to come back to this committee and to the Congress periodically and ask to have individual antibiotics added to the law.

Our only reason for not presenting it at this time is that we have not yet reached a stage in our efforts to draft such an amendment where we can come to you with a unanimous agreement of the industry and ourselves. We would rather try to work these things out with the industry instead of offering a bill here that might be opposed by the manufacturers.

Mr. HINSHAW. That is a perfectly good reason. That is all, Mr. Chairman.

Mr. SADOWSKI. Are there any further questions, gentlemen? If not, I believe that will be all, Dr. Dunbar; and we thank you.

I do not believe we have any witnesses scheduled in opposition to this bill. Are there any other witnesses to be heard on H. R. 3151? If not, that will close the hearings on this particular bill and we will proceed to the consideration of the next bill on our calendar.

(The subcommittee proceeded to the consideration of H. R. 562.)

Mr. SADOWSKI. The subcommittee will be in order. We have up for consideration H. R. 562, a bill introduced by Mr. Van Zandt to amend section 801 (d) of the Federal Food, Drug, and Cosmetic Act, as amended, in relation to exports. We will insert at this time a copy of H. R. 562.

(H. R. 562 is as follows:)

[H. R. 562, 81st Cong., 1st sess.]

A BILL To amend section 801 (d) of the Federal Food, Drug, and Cosmetic Act, as amended, in relation to exports

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That subsection (d) of section 801 of the Federal Food, Drug, and Cosmetic Act, as amended (21 U. S. C. 801 (d)), is amended to read as follows:

"(d) No proceeding shall be instituted under section 302, 303, or 304 based on an allegation that an article which has been produced for export is adulterated or misbranded if—

"(1) such article is labeled on the outside of the shipping package with the name and address of the foreign consignee or the words 'For export';

"(2) such alleged adulteration or misbranding exists solely (A) by reason of the fact that such article is not labeled in the English language, if it is labeled in the language of the country to which such article is intended for export, or (B) by reason of compliance with a requirement established by or pursuant to the law of such country, or (C) by reason of noncompliance with a quantitative requirement in any standard established or recognized by or under section 401, 501 (b), 506, or 507, if a different but corresponding requirement, with which such article complies, has been established or is recognized by or under the law of such country;

"(3) in cases referred to in subclause (B) or (C) of clause (2) of this subsection, the exporter, prior to the production of such article, obtains an authenticated copy of the currently applicable provisions of such law, or of such requirement, upon which the exporter relies; and

"(4) such exporter keeps such authenticated copy and makes it available for copying by any officer or employee of the agency on his request at any reasonable hour until three years after any export shipment is made to which such authenticated copy relates.

But if such article is sold or offered for sale in domestic commerce, this subsection shall not exempt it from any of the provisions of this Act."

Mr. SADOWSKI. We will insert in the record at this time the reports we have on H. R. 562.

(The matter referred to is as follows:)

FEDERAL TRADE COMMISSION,
OFFICE OF THE CHAIRMAN,
Washington, March 30, 1949.

Hon. ROBERT CROSSER,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D. C.

MY DEAR MR. CHAIRMAN: This is with further reference to your letter of March 22, 1949, enclosing a copy of H. R. 562, Eighty-first Congress, first session, a bill to amend section 801 (d) of the Federal Food, Drug, and Cosmetic Act, as amended, in relation to exports, introduced January 3, 1949, by Representative James E. Van Zandt of Pennsylvania, and requesting a prompt report, together with such comment as the Commission may desire to make concerning this proposed legislation. In response thereto, I wish to advise that the bill has been carefully examined and the following comment is submitted by the Commission for the information of your committee.

It does not appear that H. R. 562 would amend provisions of the Federal Trade Commission Act or any act or statute administered by this Commission, and the provisions of this bill would not affect the performance by this Commission of its duties. The proposed legislation, if enacted, would amend the Federal Food, Drug, and Cosmetic Act and would be administered by the Food and Drug Administration. It is believed that this measure will contribute to a more orderly and exact relationship in export trade relations with foreign countries that have requirements and standards, particularly for drugs, which are different from the requirements and standards of this country. The Commission is, therefore, in favor of its enactment.

By direction of the Commission.

With kind personal regards, I am

Sincerely yours,

LOWELL B. MASON, *Acting Chairman.*

APRIL 7, 1949.

N. B.—Pursuant to regulations, this report was submitted to the Bureau of the Budget on March 30, and on April 4, 1949, the Commission was informed by telephone, that there would be no objection to the submission of the report to the committee.

LOWELL B. MASON, *Acting Chairman.*

THE SECRETARY OF COMMERCE,
Washington 25, April 1, 1949.

Hon. ROBERT CROSSER,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D. C.

DEAR MR. CHAIRMAN: This letter is in further reply to your communication of January 13, 1949, requesting the Department's comments concerning H. R. 562, a bill to amend section 801 (d) of the Federal Food, Drug, and Cosmetic Act, as amended, in relation to exports.

The proposed bill would amend section 801 (d) so that the Federal Food, Drug, and Cosmetic Act, together with the regulations and standards thereunder, would apply to articles exported from this country in like manner as it applies to articles shipped in interstate commerce, except in cases where the misbranding exists solely because an article is labeled in the language of the country to which it is to be exported, rather than the English language, and in cases where the adulteration or misbranding under the standards established by the laws of this country is required in order to comply with the law of the foreign country.

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While there would undoubtedly be some cases where materials not up to standards established by the laws of this country would be prevented from moving, thereby causing financial loss in those few cases, the Department nevertheless is of the opinion that the enactment of the amendment would have little adverse effect on our domestic producers. The Department is of the opinion, however, that the proposed revision of section 801 (d) would be of benefit to American exports. Although items currently shipped in export must be in conformity with the laws of the country for which they are intended, they need not conform to American standards established pursuant to the Federal Food, Drug, and Cosmetic Act, provided they are labeled "for export." In many countries, sales of certain products have declined because purchasers have come to look upon imported American foods and drugs as being either adulterated or misbranded, even though they conform to the standards of the importing country. If the standards of our Federal Food, Drug, and Cosmetic Act, which are the highest in the world, were made applicable to our exported products, the confidence of foreign buyers in foods and drugs imported from the United States would be reestablished. While it is difficult to determine to what extent the subject provision would benefit our foreign trade, it would invite greater confidence in American products, and, as a result, it is very likely that foreign buyers would be more receptive to American products, particularly medicinals and food products.

It is, therefore, the Department's opinion that the gains in American foreign trade which would be prompted by the subject revision in our Food, Drug, and Cosmetic Act would more than offset any possible losses which would be suffered by those domestic industries which, because of the applicability of the Federal Food, Drug, and Cosmetic Act to exports, could not longer ship technically substandard products abroad, and that the enactment of such an amendment would be to the economic advantage of this country. In view of these considerations, the Department would favor the enactment of the subject legislative proposal.

I have been advised by the Bureau of the Budget that there is no objection to the submission of this report to the committee.

Sincerely yours,

CHARLES SAWYER,
Secretary of Commerce.

DEPARTMENT OF JUSTICE,
OFFICE OF THE ASSISTANT TO THE ATTORNEY GENERAL,
Washington, March 24, 1949.

Hon. ROBERT CROSSER,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D. C.

MY DEAR MR. CHAIRMAN: This is in response to your request for the views of the Department of Justice concerning the bill (H. R. 562) to amend section 801 (d) of the Federal Food, Drug, and Cosmetic Act, as amended, in relation to exports.

Section 801 (d) of the Federal Food, Drug, and Cosmetic Act presently provides an exemption for an article intended for export if it is in accordance with the specifications of the foreign purchaser, is not in conflict with the laws of the country to which it is destined, and is labeled on the outside of the shipping package to show that it is intended for export. Except for this section, articles intended for export would be subject to seizure and condemnation upon the same basis as any adulterated or misbranded article shipped in interstate commerce, and the remaining sanctions of the act would also apply.

This bill is designed to reduce drastically the scope of the exemption. It would limit the exemption to articles produced for export, as distinguished from the present exemption, which applies to articles intended for export. The exemption would be further limited so as to apply only in the following three instances:

1. Where the article is not labeled in the English language, as required by the act, but is labeled in the language of the country to which it is destined.

2. Where the condition which constitutes adulteration or misbranding under the act exists by reason of compliance with the requirements of the laws of such country.

3. Where there is noncompliance with the quantitative requirement in any standard established under the act, but compliance with a different but corresponding requirement for such standard, established or recognized under the law of the country to which the article is to be exported.

There have been very few cases involving violations of the export provisions of the Federal Food, Drug and Cosmetic Act. Since this bill would practically eliminate exemption for exports, it appears probable that the incidence of violations will increase materially.

Whether or not the bill should be enacted constitutes a question of legislative policy concerning which this Department prefers to make no comment; but, if the bill is to receive favorable consideration, it is suggested that lines 6 through 9, on page 1, be amended to read as follows:

"(d) No proceeding involving an article produced for export shall be instituted under sections 302, 303, or 304 upon the ground that such article is adulterated or misbranded it * * *."

This amendment would more clearly express the purpose of the bill which is to prevent the export of articles which would be contraband if shipped in interstate commerce except under the enumerated circumstances.

Likewise, it is suggested that the word "quantitative" be defined in the bill, or some more generally understood substitute language be used. The concept of a quantitative requirement in a food standard may, for example, be quite different from that in a drug standard.

It is also noted that the United States Code citation on line 4 of page 1 erroneously recites section 801 instead of section 381.

The Director of the Bureau of the Budget has advised that there is no objection to the submission of this report.

Yours sincerely,

PEYTON FORD,
The Assistant to the Attorney General.

FEDERAL SECURITY AGENCY,
Washington, March 16, 1949.

Hon. ROBERT CROSSER,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D. C.

DEAR MR. CHAIRMAN: This letter is in response to your request of January 13, 1949, for a report on H. R. 562, a bill to amend section 801 (d) of the Federal Food, Drug, and Cosmetic Act, as amended, in relation to exports.

The bill would require that, in general, foods, drugs, devices, and cosmetics intended for export meet the same requirements as are imposed by the law for domestic traffic in these commodities. This is in contrast to the present law which relieves any article intended for export from charges of adulteration or misbranding if it (1) accords to the specifications of the foreign purchaser, (2) is not in conflict with the laws of the country to which it is intended for export, and (3) is labeled on the outside of the shipping package to show that it is intended for export.

The bill would relax the requirements for domestic traffic only to the extent of any conflict with the law of the country of destination or to the extent that its specific standard for the article is less exacting than our standard. The bill also relieves the exported article from the requirement for labeling in the English language if it is labeled in the language of the country of destination.

Under the present law, considerable amounts of goods which, because of unfitness for human consumption, label misrepresentations, or other fault, could not be legally distributed in this country, have been exported to countries whose food and drug laws are not as advanced as ours. Many protests have been received, particularly from Latin-American countries. Because the present situation is not compatible with the good-neighbor policy and, in our judgment, is not calculated to further the reputation of American commodities in foreign commerce, this Agency favors the enactment of the bill.

We wish to call attention to an error appearing on line 4, page 1, of the bill. 801 should be 381. Also on page 2, line 24, the word "agency" should be capitalized.

The Bureau of the Budget advises that there is no objection to the submission of this report to your committee.

Sincerely yours,

J. DONALD KINGSLEY,
Acting Administrator.

DEPARTMENT OF STATE,
Washington, March 11, 1949.

Hon. ROBERT CROSSER,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives.

MY DEAR MR. CROSSER: With further reference to your letter of February 1, 1949, in which you enclosed a copy of H. R. 562, a bill to amend section 801 (d) of the Federal Food, Drug, and Cosmetic Act, as amended, in relation to exports, this Department has given consideration to the provisions of the proposed bill, the purpose of which is to strengthen the enforcement provisions of the Federal Food, Drug, and Cosmetic Act as it applies to foreign commerce, and it may be stated that this Department has no objection to its enactment.

The Department has been informed by the Bureau of the Budget that there is no objection to the submission of this report.

Sincerely yours,

ERNEST A. GROSS,
Assistant Secretary
(For the Secretary of State).

THE GENERAL COUNSEL OF THE TREASURY,
Washington, February 14, 1949.

Hon. ROBERT CROSSER,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D. C.

MY DEAR MR. CHAIRMAN: Further reference is made to the letter of your committee dated January 13, 1949, enclosing a copy of H. R. 562, a bill to amend section 801 (d) of the Federal Food, Drug, and Cosmetic Act, as amended, in relation to exports, and asking for a statement of this Department's views on this proposed legislation.

Since the proposed bill relates primarily to functions of the Federal Security Agency, and no new kinds of duties will be imposed on customs officers, the Department does not wish to make any recommendations on the merits of the bill. However, your attention is directed to an error in the bill. In line 4 on page 1 the phrase "21 U. S. C. 801 (d)" should read "21 U. S. C. 381 (d)".

Very truly yours,

THOMAS J. LYNCH,
General Counsel.

Mr. SADOWSKI. Our first witness this morning is the author of the blll, Mr. Van Zandt. We are glad to have you here, Mr. Van Zandt. You may proceed.

STATEMENT OF HON. JAMES E. VAN ZANDT, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF PENNSYLVANIA

Mr. VAN ZANDT. Mr. Chairman, first, let me express my appreciation for the opportunity to appear before you in behalf of my bill, H. R. 562, a bill to amend section 801 (d) of the Federal Food, Drug, and Cosmetic Act, as amended, in relation to exports.

Before explaining the intent of the bill, I should like to state why I introduced this legislation and also make the following corrections in the language of the bill: On page 1, line 4, change 801 to 381; on page 2, line 24, capitalize the word "agency".

On April 26, 1948, I received a communication from Mrs. Henry Deible, who is a constituent of mine from Du Bois, Pa., who, with her husband, resides in Maracaibo, Venezuela, where he is employed by the Standard Oil Co. of New Jersey. Mrs. Deible wrote as follows:

MY DEAR MR. VAN ZANDT: While participating in a study-group discussion comprised of the wives of employees of the Standard Oil Co. of New Jersey residing in Venezuela, I was surprised and shocked to learn of the laxness of the

Federal Food, Drug and Cosmetic Act which allows the export to Latin-American countries of products prohibited for sale in the United States.

The section of the law which we find most objectionable is as follows:

"SEC. 801. (d) A food, drug, device, or cosmetic intended for export shall not be deemed to be adulterated or misbranded under the act if it (1) accords to the specifications of the foreign purchaser, (2) is not in conflict with the laws of the country to which it is intended for export, and (3) is labeled on the outside of the shipping package to show it is intended for export * * *."

Besides feeling that this is not a good-neighbor policy, my interests are also selfish ones, as we, too, are the buyers of these fraudulent United States products.

We understand that a simple amendment to the law such as the following could be added:

"A food, drug, device, or cosmetic intended for export shall be deemed to be adulterated or misbranded under this act if it conflicts with the regulations governing the traffic and the sale within the United States, and such articles cannot be sold or offered for sale either within or beyond the borders of the United States."

I am appealing to you as a Representative from my home State to do all you can to correct the unfairness of this law which allows the export of these products by unreliable individuals and firms.

Thank you.

After referring Mrs. Deible's letter to the Federal Security Agency and as a result of several telephone conversations with officials of that Agency, it was deemed necessary to introduce legislation to correct the situation complained of by Mrs. Deible.

The bill will require that, in general, foods, drugs, devices, and cosmetics intended for export meet the same requirements as are imposed by the law for domestic traffic in these commodities.

Under existing law, considerable amounts of goods that cannot be sold in this country for various reasons are exported to countries whose food and drug laws are not as stringent as similar laws of the United States.

When calling Mrs. Deible's protest to the attention of the Federal Security Agency, I was informed many protests had been received and particularly from Latin-American countries. This being the case, it would appear that remedial action is necessary, because it hampers the good-neighbor policy of our country.

Then, too, we should take into consideration that, if we export goods unfit for human consumption and allow them to be improperly labeled, most certainly we are doing great harm to the reputation of American commodities in foreign commerce.

Based on information furnished me by the agencies of our Federal Government concerned with this legislation, there is no objection to the passage of this bill. It is my hope that this committee will give it favorable consideration.

I understand Dr. Dunbar of the Food and Drug Administration is present and will go into further details of the bill with the committee.

Mr. SADOWSKI. That is our understanding. Thank you, Mr. Van Zandt, for your statement. Are there any questions?

Mr. ROGERS. May I ask you one question? Why should we pass a law that would prohibit the shipment of any article to a nation which has a less strict standard than we have?

Mr. VAN ZANDT. I am sorry, sir; I did not quite hear all of that question. Would you mind repeating it?

Mr. ROGERS. Let me put it this way. Suppose the specifications under the foreign law were less exacting than our standards. Why should we pass a law to prohibit a shipment of certain drugs to other nations if that be the case?

Mr. VAN ZANDT. I think that question can be answered by the fact that we have an American citizen in Venezuela who made a purchase of an American commodity and she found that it represented what we would consider the poorest to be obtained on the market in the United States. The grade was so low that she felt that she was not buying what she had in mind to buy, but something else. It was unfit for use. And it was for that reason that she felt that these articles should be labeled so that she, an American citizen, should be able to determine by looking at the label exactly what she had purchased.

I think also that while a commodity produced by a local manufacturer in Venezuela, let us say, may not be as good as a similar commodity produced in this country, and sent to that country, yet the commodity sent there should be labeled and its contents made known to its purchasers so that the reputation of our commodities in foreign commerce may be maintained at its highest level.

Mr. ROGERS. She should not expect the same protection in a foreign country that she would get in her own native land, should she? Just take the particular case which you mentioned.

Mr. VAN ZANDT. I would say "Yes," Mr. Rogers. In my travels—and I have covered the world several times—when I buy an American commodity I feel that I am purchasing the best and, if I get something that is not the best, it not only disappoints me, but it naturally hurts the feeling that I have for the American manufactured commodities.

Mr. DOLLIVER. Mr. Van Zandt, what class of manufacturers or exporters would be hurt by this kind of legislation, if anybody?

Mr. VAN ZANDT. I am not in a position to answer that question. I shall have to refer that question to Mr. Dunbar.

Mr. DOLLIVER. Would you be willing to go along with this kind of a statement, that if standards are set up which exporters must meet, then actually the legislation will not hurt anybody except the chiseler?

Mr. VAN ZANDT. That is correct.

Mr. HINSHAW. That fellow could palm off a certain grade of goods in a foreign market perhaps under his first-grade label that would be necessary in the United States?

Mr. VAN ZANDT. Yes; that would be possible, also. Of course, to revert back to the integrity of the producer: I imagine that our Federal Government would have some control over the use of the label and if it is found that an inferior commodity has been sent abroad under a label that would not indicate just what it was, I should think there is a provision of existing law that would be violated by that individual.

Mr. HINSHAW. It is true, is it not, that there are some products which seem to have a very ready market in foreign countries that would not be permitted to be sold on the domestic market as being in violation of the Food, Drug, and Cosmetic Act while at the same time they are liked elsewhere?

Mr. VAN ZANDT. That is true. But I still think they should be labeled first to let the purchaser know what he is getting, and second, I think to uphold the reputation of American manufactured goods.

Mr. HINSHAW. That is all, Mr. Chairman.

Mr. SADOWSKI. Thank you, Mr. Van Zandt. Our next witness is Dr. Dunbar.

STATEMENT OF DR. P. B. DUNBAR, COMMISSIONER OF FOOD AND DRUGS, FOOD AND DRUG ADMINISTRATION

Dr. DUNBAR. Mr. Chairman, before I present my prepared statement, I would like to show you some specimens of products collected for us by representatives of the State Department in several South American countries, and comparable products of the same manufacturer produced and sold in the United States. You will note the vast difference in the labeling claims particularly in the case of drug products as between the exported and the domestic product.

Let me explain that in most cases you have two samples. One bears the English label prepared for the distribution of the product in the United States and the other bears ordinarily a Spanish label intended for use on the exported product. Attached to the packages you will find a typewritten sheet. One is marked domestic labeling and the other export labeling and the pertinent portion at least of the export labeling has a translation attached. I think you will find those specimens quite enlightening.

Now, if I may present my prepared statement, Mr. Chairman.

Mr. SADOWSKI. Yes; you may proceed, Dr. Dunbar.

Dr. DUNBAR. H. R. 562 would amend the Federal Food, Drug, and Cosmetic Act by requiring that food, drugs, devices, and cosmetics intended for export meet the same requirements as the law sets up for domestic traffic in these commodities. Exceptions would be made where the law of the country of destination conflicts with ours or where a standard specified by the foreign law is less exacting than our standard.

May I interrupt my prepared statement, Mr. Rogers, to point out that that I think is the answer to your query because, if the product is being shipped to a country which has its own law applicable to that product, then that law and that standard of that country will apply and there will be no violation of our statute; that is, if the product is shipped to the foreign country and complies with the laws of the country to which it is going.

A final exception would relieve exported articles labeled in the language of the country of destination from the requirements that articles in domestic commerce be labeled in the English language.

The present law, in section 801 (d), provides that:

> A food, drug, device, or cosmetic intended for export shall not be deemed to be adulterated or misbranded under this Act if it (1) accords to the specifications of the foreign purchaser, (2) is not in conflict with the laws of the country to which it is intended for export, and (3) is labeled on the outside of the shipping package to show that it is intended for export. * * *

It should be noted that the comprehensive definitions of "adulterated" and "misbranded" in sections 402, 403, 501, 502, 601, and 602 include among other things articles which are poisonous or deleterious to health; those which are filthy, decomposed or putrid, or which have been prepared under insanitary conditions; those in which substitutions have occurred or which fall below their professed quality or strength; those which are labeled with false or misleading representations and, in the case of drugs and therapeutic devices, those which fail to bear adequate directions for use and adequate warnings against probable misuse.

The scope of the exemption becomes apparent, as does its significance, when we recognize that the laws of this country on foods, drugs and cosmetics are more advanced in their consumer-protective features than the laws of any other country. Many of the smaller countries do not have the scientific and technical resources required for effective enforcement in the highly technological field of food and drug production and distribution.

The problems at which this bill is directed began to receive national and international attention when a sensational article entitled "Quarantine for Dr. Quack" was published in the English and Spanish editions of the Reader's Digest for October and December 1946, respectively. After quoting the text of section 801 (d) of the Food, Drug, and Cosmetic Act the author comments:

> Because of such loopholes, dozens of concoctions barred in the United States are sold to our unsuspecting neighbors.

Then follow a number of specific instances of allegedly unworthy merchandise exported to Latin-American countries. One cited is that of—

> a Chicago manufacturer who concocts a dangerous abortifacient, capable of producing serious or even fatal consequences. Barred from selling his dope in the United States, he swapped English labels for Spanish and is making his fortune in Latin America.

The author quotes Dr. Oscar Vargas, health official of Costa Rica, as explaining to the pan-American delegates to the World Health Conference that—

> The smaller republics cannot afford to operate large laboratories for analyzing imported patent medicines. * * * It would put such a burden on our finances that we would have to declare prohibitive import duties in order to get the necessary income, and that in turn would put an unjust burden on exporters of high quality, honestly labeled drugs * * *.

The article concludes with the following paragraph:

> No other nation has medical health and sanitation standards as high as those of the United States. We have hundreds of reputable drug manufacturers who can export both drugs and prestige with their honest labels. They as well as the Latin-American druggists, hospitals, and consumers need protection against those who discredit the label "Made in the U. S. A."

Not only was this article disseminated in the Spanish edition of the Reader's Digest but, according to reports from several American embassies in Latin America, it was quoted and discussed widely in the press of those countries. Such reports, accompanied in some instances with a request for information on which the story could be refuted, were received through the State Department from Brazil, Venezuela, Guatemala, Peru, and El Salvador.

In its report from the last-named country, the American Embassy in commenting on the debate among Salvadorans as to measures that should be taken, said:

> Regardless of this disagreement on method, the current press campaign touched off by Reader's Digest has apparently consolidated opinion that improved controls on drug imports and distribution are required. It can accordingly be assumed that more stringent regulations will be forthcoming and that such controls will work hardship on the legitimate American drug exporter as well as those who may have profited from the sale abroad of pharmaceuticals banned in the United States. The effect of the Reader's Digest article may, accordingly, be to penalize the vast majority of legitimate American drug exporters in the course of correcting the alleged misdemeanors of a small minority.

The American Embassy in Guatemala submitted a translation from a prominent local newspaper in which it was asserted that:

> The United States has for the use of its population laws which jealously protect it against medicinal fraud; but, no less jealous of its economic interests and its always favorable balance of payments, with inhuman tolerance it foments the industry of therapeutical charlatans looking toward the horizons of exportation, which does not agree with the most elemental principles of civilization of the century * * *.

and then adds, sarcastically—

> if fraudulent drugs are producing cash income for the United States, let them be exported in good time to Latin America and in that manner prove the bragged-about good-neighbor policy.
>
> In these countries we do not have scientific bulwarks to defend the people from this avalanche of fraudulent and infamous nonethicals * * *.

In addition to critical expressions of foreign nationals, a great many letters of protest have been received from citizens of the United States temporarily residing in Latin-American countries. Typical of these is the following letter addressed in early 1948 by Mrs. Lawrence E. Caldwell, Maracaibo, Venezuela, to a Member of Congress:

> While participating in a study-group discussion comprised of the wives of employees of the Standard Oil Co. residing in Venezuela, I was surprised and shocked to learn of the laxness of the Federal Food, Drug and Cosmetic Act which allows the export to Latin-American countries of products prohibited for sale in the United States.
>
> Besides feeling that this is not a good-neighbor policy, my interests are also selfish ones as we, too, are the buyers of these fraudulent United States products.
>
> We understand that a simple amendment to the law could be added to eliminate this situation.

One of the conditions set up by section 801 (d) for the exemption of exports from the prohibition against adulteration and misbranding applicable to domestic commerce is that the article comply with the laws of the country of destination. To determine with sufficient certainty that this condition has not been met is difficult and time consuming. Authoritative interpretations of the applicability of a foreign law to a specific product shipped at a specific time cannot be ordinarily obtained except from executive or judicial officers of the foreign country. If criminal prosecution is brought against a person for exporting an article alleged not to comply with the exemptions of 801 (d) the proof of noncompliance would ordinarily require testimony of a foreign official or his authorized representative in this country, if any.

In view of this situation, and because of the pressing demands of enforcement far exceeding our facilities against abuses of consumer welfare in domestic commerce, the Food and Drug Administration has remained substantially inactive with respect to export goods. In the few instances in which we have made investigations, the requisite proof for legal action could not be obtained.

Recently the State Department was asked to collect samples of certain classes of American drugs on Latin-American markets for the purpose of comparing them and the representations made for them in foreign countries with the composition and labeling of the same products sold in domestic commerce. While this survey is not complete it is apparent that in a number of instances the label representations of the exported product differ strikingly from those of the domestic product put out by the same manufacturer. This was

also found to be true with respect to samples obtained during factory inspection of a few plants in this country producing for both export and domestic commerce.

One of the samples that I placed on your desk is one of the few specimens of a food product that we have encountered that is an entirely fictitious product. It is labeled as almond oil for export only. Actually it is cottonseed oil synthetically flavored with benzaldehyde. That, of course, would be entirely illegal if sold as almond oil in this country, but under the terms of the present law, the present export section, it could be exported under the label which you see there.

In testifying before the Senate Committee on Commerce on the export provisions of a bill which was finally enacted into the Food, Drug, and Cosmetic Act of 1938, Mr. W. G. Campbell, Chief of the Food and Drug Administration, then a unit of the Department of Agriculture, said:

> Now, Senator, there is not a doubt in the world that there is greater diligence in the enforcement of laws regulating food and drug products in America than anywhere else. American products are bought extensively on that understanding. That very fact, in and of itself is an asset to American producers, and it is calculated to give preference to American products in the foreign markets of the world.
>
> My thought is this Without undertaking any undue solicitude about the welfare of consumers in other nations, it would be inhuman not to restrict the shipment of products that would be deleterious to health to the foreign consumers, products that we would not permit to be marketed in this country; also products which are filthy, putrid, or decomposed. If that practice is permitted on the part of a few who might desire to do it, it would compromise the standing and the reputation of American food and drug producers.

This expression represents our present views. The export provision of the law as it now stands is not compatible with the good-neighbor policy and is not calculated to further confidence of foreign buyers in American-made goods. This agency favors the enactment of H. R. 562.

May I just add a few words to my prepared statement, Mr. Chairman and gentlemen? The American manufacturers of foods, drugs, and cosmetics, all of the products that are subject to this law, are the most capable manufacturers in the world and America has the finest and purest supplies of these articles, the most honestly labeled of any country in the world.

It is my conviction that the vast majority of American manufacturers are complying with the terms of this statute because not only do they know it to be good business and the law, but they are honest individuals who believe in putting out honest and pure articles. To the extent that the present export provisions permit the few who are inclined to cheat the consumer to ship to foreign countries, articles of the type that you have before you there, medicines which would not be permitted to be sold in this country except under very minor medicinal claims, but which are represented abroad as having extreme curative properties—to the extent that those products are permitted free distribution overseas or in South America, the honest, reputable manufacturer who is trying to build up a reputation for his legal product is denied a satisfactory market. And from the standpoint of the good-neighbor policy certainly I can find no argument against supporting Mr. Van Zandt's bill, because there is no justification whatsoever for our using foreign countries as a dumping ground for products that we consider unfit for use in the United States.

Thank you, Mr. Chairman.

Mr. SADOWSKI. Are there any questions, gentlemen?

Mr. HINSHAW. I think Dr. Dunbar has mentioned two different subjects in the last sentence. The first was the fact that claims were made in a foreign language that were not sustainable under our own Food, Drug, and Cosmetic Act, and so we should not permit the labeling and the inclusion in the package of statements of that character. That is one statement. The other statement was that we should not permit the export of articles which were obviously of inferior quality to those which were used in the United States. Now, you stand by both of those statements?

Dr. DUNBAR. I stand by both of those statements with this qualification, that if there are laws in the foreign country that permit a different quality—for instance, they may have an entirely different standard for food products or for drugs such as we have under the United States Pharmacoepia. They may have a Brazilian Pharmacoepia—I do not know that they have, but if they did, it might set up a different standard in that country and certainly we should not insist that our standard apply to products going into that country.

Mr. HINSHAW. To those who have traveled in foreign countries it is quite obvious that not only drugs of various kinds but also physicians who are also of various kinds and characters, treat their professional duties differently from the way they are treated here in the United States. You will find physicians in Latin-American countries advertising all kinds of cures, with great big signs hung out in front of their offices. We do not find that in the United States. It is not ethical in the medical profession in the United States to do such advertising. But all one needs to do is to walk down a street in Rio de Janeiro or Lima, Peru and see those signs. Obviously, they go to lengths in advertising or misadvertising, if you please, which we would not permit in this country either by law or under the ethics of the profession.

I suppose that the manufacturer might claim that he would be hurt in trying to sell his product down there by the mere virtue of the fact that he was not able to lie as much as the other fellow; is that true?

Dr. DUNBAR. I think that would be one argument against this proposed measure, yes. In other words, if everybody is lying down there, why should not I have a chance to do the same thing?

Mr. HINSHAW. I assume that is what they would think.

Dr. DUNBAR. Yes, sir.

Mr. HINSHAW. At the same time I certainly agree with you that the quality of the product and its lack of deleterious effect should be considered in the legislation. I do not know about the rest of it. I have seen some of the lies put out in that language down there by ostensibly reputable physicians and also I suppose used by purveyors of food and drugs sold in the market place that are not necessarily of American manufacture at all.

Dr. DUNBAR. Mr. Hinshaw, I realize that the Food and Drug Administration cannot reform the entire world. I think your comments on the situation as it exists in some of these countries are very pertinent. They do not have the standards of sanitation or medical practice that we have in the United States. Nevertheless, I feel from the standpoint of ethics and good business that we should not permit

our manufacturers to indulge in that type of misrepresentation that may prevail in some of the medical circles in some of these South and Central American countries. Many of them represent very serious dangers to public health and just because the local traffic is doing it is no reason why we should encourage its being done by our own manufacturers in this country, for shipment abroad.

Mr. ROGERS. Dr. Dunbar, would you say the provisions of this bill will take care of the situation mentioned by you, to provide an exception where the standard of the foreign country is less than our standard?

Dr. DUNBAR. It is my interpretation, Mr. Rogers, that paragraph 2 on page 2 of the bill takes care of that. It reads:

> (2) Such alleged adulteration or misbranding exists solely (A) by reason of the fact that such article is not labeled in the English language, if it is labeled in the language of the country to which such article is intended for export, or (B) by reason of compliance with a requirement established by or pursuant to the law of such country, or (C) by reason of noncompliance with a quantitative requirement in any standard established or recognized by or under section 401, 501 (b), 506, or 507, if a different but corresponding requirement, with which such article complies, has been established or is recognized by or under the law of such country;.

I think that covers it.

Mr. KEOGH. Mr. Chairman, I do not want to ask the Doctor any question, but I want to say, Doctor, that in your statement you paid your compliments to the vast majority of manufacturers of food, drugs, and cosmetics. From what I have learned from my brother, who is the United States attorney in Brooklyn, I think the same high compliments can be paid to your staff who are ever diligent in protecting the American public.

Dr. DUNBAR. Thank you very much, Mr. Keogh. That is a very pleasant compliment and we appreciate it. And furthermore, we have had some very wonderful support from the United States attorney in Brooklyn.

Mr. SADOWSKI. Gentlemen, there has been a call of the House and it will be necessary to adjourn this hearing until tomorrow morning. We shall meet tomorrow at 10 o'clock and should like you to return at that time, if you will, Dr. Dunbar.

(Whereupon at 11:15 a. m., the subcommittee adjourned to meet on Wednesday, April 13, 1949, at 10 a. m.)